

REMARKS

Summary of the Invention

The present invention features a method for determining the prognosis of a patient diagnosed with Alzheimer's disease. The method is performed by determining the patient's *apoE* allele load, in which the presence of an *apoE4* allele or ApoE4 protein isoform indicates that a patient will respond poorly to a cholinomimetic agent.

Summary of the Office Action

Claims 1, 3, 5-8, and 10-14 are pending. Claims 1, 3, 5-8, and 10-14 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,935,781 (hereinafter "the '781 patent"). By this reply, Applicant cancels claims 5-8 and 10, amends claim 1, and addresses each of the Examiner's rejections below.

Information Disclosure Statement

Applicants enclose a supplemental information disclosure statement and 1449 form listing Landen et al. (*Dementia* 7:273-278, 1996); a copy of which is provided. Landen et al. was cited in the 1449 form filed with the supplemental information disclosure statement on August 13, 2004, but a copy of Landen et al. was inadvertently excluded from the submission. Applicant respectfully requests that this reference be considered.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 3, 5-8, and 10-14 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states:

The disclosure describes a method for creating a prognostic protocol for late onset Alzheimer's disease (AD) patients by examining ApoE protein levels...Applicants were advised that appropriately drafted claim language directed toward this embodiment would be acceptable.

Office Action, p. 2.

Applicant respectfully disagrees, however, in an effort to expedite prosecution, Applicant has amended independent claim 1 to now recite a method of determining the prognosis for a patient diagnosed with Alzheimer's disease (AD). Because present claim 1, and claims dependent therefrom, recite subject matter deemed allowable by the Examiner, the rejection of claims 1, 3, 5-8, and 10-14 may now be withdrawn.

Rejection for Obviousness-Type Double Patenting

Claims 1, 3, 5-8, and 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of the '781 patent. The Examiner states:

As previously set forth, the claims of the instant application are directed toward prognostic protocol methods involving patients with neurological disorders and *apoE* allele load determinations while the claims of the '781 patent are directed toward patient prognostic protocols involving patients with cognitive impairments, which are caused by CNS pathologies. Thus, the claims of the '781 patent fall within the scope of the claimed invention and would result in the unjustified or improper timewise extension of the "right to exclude" granted by a patent.

Office Action, p. 8. Applicant respectfully traverses this rejection.

The M.P.E.P. § 804(II)(B)(1) states that, in cases where an obviousness-type double patenting rejection has been made, "the first question to be asked is - does any claim in the

application define an invention that is merely an obvious variation of an invention claimed in a patent? If the answer is yes, then an ‘obviousness-type’ nonstatutory double patenting rejection may be appropriate.” The M.P.E.P. § 804(II)(B)(1) also states that:

A double patenting rejection of the obviousness-type is “analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. 103” except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The question of obviousness, in cases of double patenting, is addressed using the criteria established under 35 U.S.C. § 103. A finding of obviousness under 35 U.S.C. § 103 is only affirmed if all of the claim limitations are taught or suggested in the cited patent or patents on which the rejection is based (*In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). The patent specification cannot be used as prior art and obviousness must be determined based solely on the claims of the ‘781 patent (see *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970)).

Furthermore, the case law is clear with respect to genus-species relationships: “the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness (*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)); “[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious” (*In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992))).

Present claims 1, 3, and 11-14 are directed to a method of determining the prognosis for a patient diagnosed with Alzheimer’s disease (AD) by identifying a patient already diagnosed with AD and determining the patient’s *apoE* allele load by genotyping or phenotyping, in which the

presence of at least one *apoE4* allele or at least one ApoE4 protein isoform is indicative of a poor patient outcome. In contrast, claims 1-4 of the '781 patent are directed to a method for the identification of human subjects with cognitive impairments to be responsive to a cholinomimetic drug by determining the number of copies of apoE4 gene alleles in the subject, in which the absence of at least one apoE4 gene allele indicates a predisposition to respond to a cholinomimetic drug. The term "cognitive impairment" can be used to describe a broad genus of diseases and disorders that affect the functioning of the brain, many with entirely distinct etiologies. AD is but one disease known to the skilled artisan that is characterized by cognitive impairments. Because the claims of the '781 patent are the only "prior art" that can be examined in an obviousness-type double patent rejection and because the claims of the '781 patent do not teach or suggest that the method can be employed with AD patients, the skilled artisan would have no basis to select AD patients from among the genus of patients having cognitive impairments for use in the method. Thus, absent the necessary teaching or suggestion in the claims of the '781 patent, AD patients cannot be considered an obvious variant of patients having cognitive impairments.

Moreover, the rejection of claims 1, 3, and 11-13 for obviousness-type double patenting is improper because the method recited in present claims 1, 3, and 11-14 represents a non-obvious species of the broader genus of the method recited in claims 1-4 of the '781 patent. As is clear from *In re Baird* and *In re Jones, supra*, the mere fact that the present claims recite a species of patients that fall within the genus of patients recited in the claims of the '781 patent does not provide a sufficient basis for a double patenting rejection.

Based on the foregoing remarks, Applicant respectfully requests that the rejection of claims 1, 3, 5-8, and 10-14 for obviousness-type double patenting over claims 1-4 of the '781 patent be withdrawn.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested.

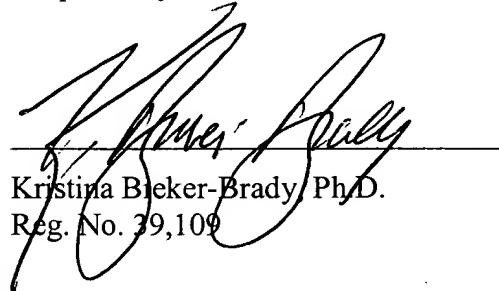
Enclosed is a Petition to extend the period for replying for three months, to and including May 2, 2005, and a check for the fee required under 35 U.S.C. § 1.17(a).

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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